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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/813,904	03/31/2004	Iain H. Kalfas	101896-366 (DEP5181)	5037

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EXAMINER

YANG, ANDREW

ART UNIT	PAPER NUMBER
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3733

NOTIFICATION DATE	DELIVERY MODE
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10/03/2007

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docket@nutter.com

Office Action Summary	Application No. 10/813,904	Applicant(s) KALFAS ET AL.	
	Examiner Andrew Yang	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-35 and 56-63 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-35 and 56-63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 July 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>7/13/2007</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is in response to Applicants' amendment filed on July 13, 2007.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 17-20, 29, 56, and 60-63 are rejected under 35 U.S.C. 102(b) as being anticipated by Gelbard (U.S. Patent No. 5397363).

Gelbard discloses a spinal stabilization system with a plurality of bone anchors 12, a rod 28 connecting at least two bone anchors 12, and a connecting plate 36 extending from a proximal surface of the bone anchors 12. The bone anchors 12 are monoaxial and have a distal portion 16 and a rod-receiving portion 26 that defines the proximal surface. The connecting plate 36 has openings 42 at a first end 38 and openings 44 at a second end 40 for attachment to the bone anchor and a spanning portion extending connecting the first end 38 to second end 40 (Figure 1). Furthermore, the plate 36 and rod 28 are oriented at an angle of about 90 degrees (Figure 1).

With reference to Figure 1, the device is used to fix vertebrae by attaching a plurality of bone anchors into adjacent vertebra. More specifically, a pair of anchors 12 is attached to a first vertebra, and a second pair of anchors 12 is attached to a second vertebra. The anchors 12 that are not attached to the same vertebra are connected by

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rod 28 and the anchors 12 that are attached to the same vertebra are connected by plate 36.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4-11, 15, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gelbard (U.S. Patent No. 5397363) in view of Dinello et al. (U.S. Patent No. 5522816).

Gelbard discloses the claimed invention except for a set screw threadingly engaging the rod receiving portion and a cap that threadingly engages the set screw and a buttress at a distal side of the spanning portion. Dinello teaches a spinal corrective device with members 34, rods 10, and a connecting plate 30. The members 34 have a rod-receiving portion 40 and an opening 46 for receiving a set screw 48. Set screw 48 is used to clamp the rod against surface 42 of the rod-receiving portion 40. The plate 30 with openings 56 at each end and are placed over the set screw 48 which is then engaged by a cap 74 to clamp the plate 30 to members 34. The plate 30 also has buttress portions 58 at a distal end of the plate and is in place for preventing the plate 30 from pivoting relative to the members 34 (Column 3, Lines 15-19). It would have been obvious to one skilled in the art at the time the invention was made to

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construct the device of Gelbard with a set screw threadingly engaging the rod receiving portion, a cap to engage the set screw, and a buttress at an end of the plate in view of Dinello et al. in order to clamp the rod and plate to the members which they contact, and also to prevent the plate from pivoting relative to the member it is connected to.

With regard to claim 16, Dinello et al. discloses the set screw engaging a bore defined by the cap. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have a cap that engages a threaded bore defined by the set screw, since it has been held that a mere reversal of the essential working parts of a device involves only routine skill in the art. In re Einstein, 8 USPQ 167.

With regard to claims 9-11, Gelbard fails to disclose the connecting plate having a distal bearing surface that is domed with a spherical or conical shape. It would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the distal bearing surface of the connecting plate have a distal bearing surface that is domed, with a spherical or conical shape, since applicant has not disclosed that such solve any stated problem or is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of providing a forming edge in the heating portion or clamp. In re Dailey and Eilers, 149 USPQ 47 (1966).

Claims 12-14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gelbard (U.S. Patent No. 5397363) in view of Dinello et al. (U.S. Patent No. 5522816) and further in view of Bono et al. (U.S. Publication No. 2004/0087949).

Gelbard and Dinello et al. disclose the claimed invention except for a floating washer with a bearing surface that mates with the distal bearing surface of the cap, and rails that slidably engage the connecting plate. Bono et al. teaches a spinal fixation system with a plate 1 having a bone anchor portion 10 and a washer 30. Washer 30 has projections 34 which are for engaging channels 14 of the bone anchor portion 10. (Paragraph 32). A bone anchor can then be placed through the hole 32 of the washer, and by use of locking nut is held by compression between the washer and the bone anchor (Paragraph 30). The washers of the assembly minimize the number of parts a surgeon may have to handle during surgery (Paragraph 29). It would have been obvious to one skilled in the art at the time the invention was made to construct the device of Gelbard in view of Dinello et al. with a floating washer having rails that slidably engage the connecting plate further in view of Bono et al. in order to minimize the number of parts a surgeon has to handle during surgery.

Claims 30-33, 57 and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gelbard (U.S. Patent No. 5397363) in view of Mathis et al. (U.S. Publication No. 2004/0186474).

Gelbard discloses the claimed invention except for using polyaxial screws that have a radius of curvature about a point which the bone screw pivots for the bone anchors. Mathis et al. teaches an implant for use in spinal surgery that uses a polyaxial screw with a spherical head 2, held in rod receiving portion 3. The head has a radius of curvature about a point which the bone screw pivots. The use of the polyaxial screw is so that the angular position of the screw can be changed relative to the receiver portion

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3 (Paragraph 38). It would have been obvious to one skilled in the art at the time the invention was made to construct the device of Gelbard with bone anchors that are polyaxial screws in view of Mathis et al. so that the angular position of the bone anchors could be adjusted.

Claims 21-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gelbard (U.S. Patent No. 5397363) in view of Dove et al. (U.S. Patent No. 5366455).

Gelbard discloses the claimed invention except for a plate that has a spanning member that is arcuate in shape and a hole that is circular or elliptical in shape. Dove et al teaches a spinal fixation device with bone anchors 29, a rod 26, and a plate 10. The plate has a spanning portion 11 that is curved and is also offset from a planed defined by the end 13 of the plate 10 to allow clearance for the spinous processes (Column 2, Lines 62-65) and a hole 14 that is substantially elliptical (Figure 2) to receive a screw (Column 2, Lines 42-44). It would have been obvious to one skilled in the art at the time the invention was made to construct the device of Gelbard et al. with a curved spanning portion and an elliptical hole in view of Dove et al. so that the plate will have clearance for the spinous processes and to receive screws..

With regard to the radius of curvature and the distance that the spanning portion is offset from the end of the plate, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the spanning portion of Gelbard with a radius of curvature between 8mm and 12mm or 5mm and 15mm and offset at least 3mm and between about 5mm and 10mm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the

optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claims 34, 35, and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gelbard (U.S. Patent No. 5397363) in view of Mathis et al. (U.S. Publication No. 2004/0186474) and further in view Dinello et al. (U.S. Patent No. 5522816).

Gelbard and Mathis et al. disclose the claimed invention except for a set screw that threadingly engages the rod receiving portion and a cap that threadably engages the set screw and a compression member between the rod and the bone screw. Dinello et al. teaches a spinal corrective device with members 34, rods 10, and a connecting plate 30. The members 34 have a rod-receiving portion 40 and an opening 46 for receiving a set screw 48. Set screw 48 is used to clamp the rod against surface 42 of the rod-receiving portion 40. The plate 30 with openings 56 at each end and are placed over the set screw 48 which is then engaged by a cap 74 to clamp the plate 30 to members 34. It would have been obvious to one skilled in the art at the time the invention was made to construct the device of Gelbard in view of Mathis et al. with a set screw threadingly engaging the rod receiving portion, a cap to engage the set screw further in view of Dinello et al. in order to clamp the rod and plate to the members which they contact.

With regard to claim 35, Mathis et al. teaches a compression element 10 for fixation of the angular position of the polyaxial screw. It would have been obvious to one skilled in the art at the time the invention was made to construct the device of

Gelbard with a polyaxial screw with a compression member in view of Mathis et al. so that the angular position could be fixed.

Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gelbard (U.S. Patent No. 5397363) in view of Dove et al. (U.S. Patent No. 5366455) and further in view of Pisharodi (U.S. Patent No. 6355038).

Gelbard and Dove et al. disclose the claimed invention except for the opening of the connecting plate being open ended. Pisharodi teaches a spinal fixation assembly with a plate 32 having an open-ended hole 44 for facilitating assemble of the plate 32 to screws 34. It would have been obvious to one skilled in the art at the time the invention was made to construct the device of Gelbard in view of Dove et al. with a plate having a hole with an open end further in view of Pisharodi in order to facilitate assemble of the plate to the bone anchors.

Response to Arguments

Applicants contend that Gelbard does not disclose a connecting plate extending from a proximal surface of a rod-receiving portion of a bone anchor. The Examiner respectfully disagrees. It is considered that the rod-receiving portion of Gelbard can be divided into upper and lower halves (proximal and distal sections). The connecting plate engages the rod-receiving portion on a surface in the proximal section of the rod-receiving portion and thus extends from a proximal surface of the rod-receiving portion.

Applicants contended that the secondary references cited by the Examiner does not teach a connecting plate that extends from or rests against a proximal surface of a rod

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receiving portion. it has been disclosed above that the connecting plate of Gelbard extends from a proximal surface of a rod-receiving portion and the secondary references need not provide a teaching for a plate extending from a proximal surface of a rod receiving portion. The secondary references provide teaches to their respective dependent claims.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication from the examiner should be directed to Andrew Yang whose telephone number is 571-272-3472. The examiner can normally be reached Monday-Friday 7:30 am – 5:00 pm EST.

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If attempts to reach the examiner by telephone are unsuccessful the examiner's supervisor, Eduardo Robert can be reached at 571-272-4719. The fax number for the organization where this application is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private Pair only. For More information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact Electronic Business Center (EBC) at 866-217-9197 (toll free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (USA OR CANADA) or 571-272-1000.

A.Y.

9/18/2007



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